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CHRONIC OBSTRUCTIVE PULMONARY DISEASE

National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care

Developed by

The National Collaborating Centre for Chronic Conditions

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The following versions of this guideline are also available:

NICE Guideline	www.nice.org.uk/CG012niceguideline
Quick Reference Guide	www.nice.org.uk/CG012quickrefguide
Information for Patients	www.nice.org.uk/CG012publicinfo

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Preface

COPD is common but for many years was largely ignored on the (false) grounds that little could be done. However in the last 10 years there has been a surge in research interest and several new treatment options. The first Guidelines on the Management of COPD (published by the British Thoracic Society in Jan 1997) led to significant improvements in the recognition and care of COPD. Since then new treatment possibilities including long-acting bronchodilator drugs, respiratory rehabilitation services, and non-invasive ventilation in respiratory failure, have meant that a revision is overdue.

The guideline was commissioned from NICE and the scope for the project was developed by the National Collaborating Centre with input from all the stakeholders registered with NICE. The agreed final project scope advises that since it is aimed at the NHS, the guideline should concentrate on the health aspects of COPD. However it should also include the need for support from other agencies including social services, and should set out the interface with such services but not discuss their detailed provision.

There are other national and international guidelines for COPD but this is the first to systematically bring together and examine all the evidence in the published literature. The systematic nature of the approach provides an explicit audit trail of what has and has not been identified and how it was treated. Because the project scope was so wide ranging, even with an extremely hard working and dedicated team, it has not been possible to examine every paper on every question. Pragmatic choices have had to be made. Thus we searched first for the best quality research studies and if several were found that provided a strong evidence base, did not continue to search for papers of lesser quality. The searching for, and systematic critical appraisal of, studies has been done using standard techniques and all searches will be available to future researchers. We believe it is unlikely that important papers have been missed either by the technical team in their searches or by the expertise of the guideline groups.

The guideline had to cover all aspects of the disease so that local care pathways could be defined using the document. Where there were gaps between the evidence, these have been filled with best practice recommendations based on a formal consensus of the experts on our guideline groups.

In each section of the document the level of supporting evidence is made clear on the understanding that the stronger the evidence the greater likelihood that the recommendations based on it are sound. **However the reader should not equate level of evidence with strength of recommendation - some of the most important recommendations with greatest consequences for the health service or for people with COPD have been made by group consensus because there was inadequate evidence. This is what the experts believe to be best practice i.e. what they would recommend for their patients or relatives**.

While the detail of local implementation of this guideline may vary (according to local facilities and geography), the main aims ought to be common across England and Wales and if adopted should lead to better standards of care and thus better outcomes from this often distressing condition. But implementation will depend on both clinicians and managers working together to ensure that resources and patient needs are matched. COPD is a common disease with many

different facets to management that varies with the stages of disease and with individual patient circumstance. The evidence of the last 6 years since the first British guideline is that it is possible to work together and to improve care.

There are some recommendations that either may seem to challenge the international COPD guidelines or may rankle with individual clinicians. Our guideline group believe their recommendations to be the best advice for patient care - and hope that any who disagree will feel challenged to produce and publish evidence to either confirm or refute what this guideline sets out.

It is therefore a pleasure to welcome you to this Guideline on the management of COPD. We hope that all those involved in health care (those that commission care, those that deliver care, and the patient and carer groups) ensure that these guidelines are used and to that end we commend the audit/implementation criteria set out in the final section as ways of measuring the implementation process. Those with COPD deserve no less.

Dr Mike Pearson
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1 Introduction

1.1 Definition of chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is characterised by airflow obstruction. The airflow obstruction is usually progressive, not fully reversible and does not change markedly over several months. The disease is predominantly caused by smoking.

- Airflow obstruction is defined as a reduced FEV_1 (forced expiratory volume in 1 second) and a reduced FEV_1/FVC ratio (where FVC is forced vital capacity), such that FEV_1 is less than 80% predicted and FEV_1/FVC is less than 0.7.
- The airflow obstruction is due to a combination of airway and parenchymal damage.
- The damage is the result of chronic inflammation that differs from that seen in asthma and which is usually the result of tobacco smoke.
- Significant airflow obstruction may be present before the individual is aware of it.
- COPD produces symptoms, disability and impaired quality of life which may respond to pharmacological and other therapies that have limited or no impact on the airflow obstruction.
- COPD is now the preferred term for the conditions in patients with airflow obstruction who were previously diagnosed as having chronic bronchitis or emphysema.
- Other factors, particularly occupational exposures, may also contribute to the development of COPD.

There is no single diagnostic test for COPD. Making a diagnosis relies on clinical judgement based on a combination of history, physical examination and confirmation of the presence of airflow obstruction using spirometry. These issues are discussed in more detail in the diagnosis section (section 6).

1.2 Clinical context

Nearly 900,000 people in the UK have been diagnosed as having COPD, and half as many again are thought to be living with COPD without the disease being diagnosed. The symptoms of the disease usually develop insidiously, making it difficult to determine the incidence of the disease. Most patients are not diagnosed until they are in their fifties.

1.2.1 Prevalence

Because it is defined by airflow obstruction, questionnaire surveys cannot be used to identify patients with COPD. In the last 20 years, only one national study has measured airway function in patients aged 18-65 in the UK. Overall 10% men and 11% women had an abnormally low FEV_1 [1]. A postal study[2] with hospital assessment in Manchester in patients aged 45 and over suggested prevalence of non-reversible chronic airflow obstruction in 11%. Half of these individuals had not previously been diagnosed.

In a primary care population aged 45 and over in the UK, screened opportunistically, the prevalence of an abnormal FEV_1 and respiratory symptoms was around 9%[3]. Prevalence increases with increasing age[4] and there are significant geographic variations in the prevalence of COPD.

Unlike many other common chronic diseases the prevalence of COPD has not declined in recent years. Prevalence rates appear to be increasing steadily in women but have reached a plateau in men[5].

The best available data suggests approximately 900,000 diagnosed patients with COPD in England and Wales (table 1). Allowing for under-diagnosis, the true number of patients with COPD is likely to be around 1.5 million.

Table 1 Estimated prevalence of diagnosed COPD in England and Wales using GPRD prevalence rates & 1999 population estimates[6]

Age	Men	Women	Total
44-65	143,700	107,100	
>65	322,000	310,500	
			883,200

1.2.2 Mortality

It is difficult to be certain of the true mortality rate due to COPD. Some patients die with the disease rather than because of it. Others will die of causes related to COPD, but their death may be certified as being due to these complications[7]. Analysis of trends in death rates is also complicated by changes in the diagnostic labels.

In 1999 there were approximately 30,000 deaths due to COPD in the UK[8]. This represented 5.1% of all deaths (5.9% of all male deaths and 4.3% of all female deaths).

In men, age standardized mortality rates from COPD have fallen progressively over the last 30 years, but in women there has been a small but progressive increase over the last 20 years[5]. All cause mortality is increased in patients with COPD[6].

Even in the early 1990s mortality rates for COPD continued to show a large socio-economic bias[9].

Five year survival from diagnosis is 78% in men and 72% in women with mild disease but falls to 30% in men and 24% in women with severe disease. The mean age of death of patients with severe COPD is 74.2 years compared with 77.2 years in patients with mild disease and 78.3 years in individuals who did not have COPD[6].

1.2.3 Morbidity

The morbidity from COPD is high. Patients need frequent primary and secondary care input. Up to 1 in 8 emergency hospital admissions may be due to COPD.

Table 2 Morbidity from COPD*

	Admissions			Consultant Episodes			Days
	Men	Women	Total	15-59 yrs	60-74 yrs	>75 yrs	Total
England	77,292	22,985	97,223	18,732	64,056	67,047	1,001,211
Wales	4,840	4,126	8,967	1,428	5,363	5,339	93,711
Total	82,132	27,111	109,243	20,160	69,419	72,386	1,094,922

*Annual number of hospital admissions (by sex), consultant episodes (by age) and inpatient days for COPD (ICD J40-44) in 2002/ 2003, in England (Data from www.doh.gov.uk) and Wales (Data provided by Health Solutions Wales www.hsw.wales.nhs.uk)

The mean length of stay for patients in England for 2001-2 was 9.1 days with a median of 6 days. COPD admissions also show some seasonality and are more common in the winter months[10]. The mean length of stay for patients in Wales for 2001-2 was 10.6 days with a median of 7 days.

Consultation rates in General Practice are at least twice as high as those for angina[11]. Consultation rates rise with age from 417 per year per 1000 patients aged 45-64 to 886 per year per 1000 patients aged 65-74 and 1032 per year per 1000 patients aged 75-84[11,12]. On average a general practitioner's list will contain 200 patients with COPD. Some of these will be pre-symptomatic and remain unrecognised others may be undiagnosed. A general practitioner will suspect a new diagnosis of COPD in perhaps 20 patients annually. Those who work in more deprived areas are likely to have more cases.

1.2.4 Economic Impact

The total annual cost of COPD to the NHS is estimated to be £491,652,000 for direct costs only and £982,000,000 including indirect costs (See section 14).

Broken down by disease severity, the cost p.a. is:

- mild £149.68
- moderate £307.74
- severe £1,307.10.

The average cost per patient p.a. is £819.42, of which 54.3% is due to inpatient hospitalisation, 18.6% for treatment, 16.4% for GP and specialist visits, 5.7% for accident and emergency visits and unscheduled contacts with the GP or specialist and 5% for laboratory tests[13].

As well as these costs, it has been estimated that 21.9 million working days were lost in 1994-5. In a recent survey of a random sample of patients with COPD 44% were below retirement age and 24% reported that they were completely prevented from working by their disease. A further 9% were limited in their ability to work and patients carers also missed time from work [13].

1.3 Guideline aims

This guideline offers best practice advice on the identification and care of patients with COPD. It aims to define the symptoms, signs and investigations required to establish a diagnosis of COPD. It also aims to define the factors that are necessary to assess its severity, provide prognostic information and guide best management. It gives guidance on the pharmacological and non-pharmacological treatment of patients with stable COPD, and on the management of exacerbations. The interface with surgery and intensive therapy units (ITU) are also discussed.

1.4 Patient choice

Whenever recommendations are made, it is recognised that informed patient choice is important in determining whether or not an individual patient chooses to undergo the investigation or accept treatment that is recommended.

1.5 For whom is the guideline intended

A guideline has been defined as 'a systematically developed statement that assists clinicians and patients in making decisions about appropriate treatment for a specific condition'[14]. These guidelines are aimed at helping all healthcare professionals provide optimal services for people with COPD by:

- providing individual clinicians with a set of explicit statements on the best way to manage the most common clinical problems, and to maximise the effectiveness of the service
- providing commissioning organisations and provider services with specific guidance on the best way to organise complex services, to maximise efficiency and equity.

Others, including the general public, may find the guideline of use in understanding the clinical approach to COPD. Separate short form documents for a) the public and b) clinical staff are available which present recommendations without details of the supporting evidence.

Health commissioners

The term health commissioners has been used in this guideline to mean *Primary Care Trusts* in England and *Health Commission Wales* in Wales.

1.6 Underlying guideline principles

The main principles behind the development of this guideline were that it should:

- consider all issues that are important in the management of people with COPD
- use published evidence wherever this is available
- be useful and usable to all professionals
- take full account of the perspective of the person with COPD and their carers
- indicate areas of uncertainty or controversy needing further research.

1.7 Structure of document

The document is divided into sections, which cover a set of related topics. For each topic the lay out is similar.

The **background** to the topic is provided in one or two paragraphs that simply set the recommendations in context.

Then the **evidence statements** are given and these summarise the evidence, which is detailed in the **evidence tables**. In addition there is an evidence statement about the health economic evidence where this is available. These evidence statements and tables aim to provide context and aid the reader's understanding of why each recommendation was made.

The evidence statements are followed by **consensus statements** agreed by the guideline development group. These statements have been made when there is a lack of evidence or where the guideline development group felt that there were important issues which needed commenting on but which lay beyond or outside the current evidence base.

The main **recommendations** follow. These are graded to indicate the strength of the evidence behind the recommendation.

1.8 Guideline limitations

The document and recommendations are subject to various limitations. The commissioning authority, NICE is primarily concerned with Health Services, and so these recommendations only indirectly refer to Social Services, and the voluntary sector. Nonetheless the importance of other agencies cannot be over-stated and in each locality the aim should be to integrate COPD care across all relevant sectors.

A systematic approach was used to locate and appraise the evidence and explicit inclusion criteria were applied. Due to the magnitude of the literature potentially relevant to COPD the inclusion criteria aimed to limit the included studies to those of a higher quality conducted primarily in people with COPD. Where these were not available, well-conducted studies outside COPD or lower level studies in people with COPD were included.

The guideline usually recommends within medication licence indications. Exceptionally, where there was clear supporting evidence, recommendations, outside the licence indications have been included. As far as possible where this is the case it is indicated.

1.9 Scope

The guideline was developed in accordance with a specified scope, which detailed the remit of the guideline development and specified those aspects of COPD to be included and excluded.

Prior to the commencement of the guideline development, this scope was subjected to stakeholder consultation in accordance with processes established by NICE [15]. The scope is as follows:

Groups that will be covered

The guideline will offer best practice advice on the care of adults who have a clinical working diagnosis of COPD including chronic bronchitis, emphysema, and chronic airflow limitation/obstruction.

Groups that will not be covered

The guideline will not cover the management of people with asthma, bronchopulmonary dysplasia and bronchiectasis, nor will it cover children.

Healthcare setting

The guideline will cover the care received from primary and secondary healthcare professionals who have direct contact with and make decisions concerning the care of patients with COPD.

The guideline will also be relevant to the work, but will not cover the practice, of social services, patient support groups or palliative care services.

Clinical management

The guideline will include recommendations in the following areas.

Diagnostic criteria, including the role of spirometry in primary and secondary care.

Identification of early disease to facilitate preventative approaches.

Management of stable patients, management of exacerbations and prevention of progression of the disease, to include:

- smoking cessation, including pharmacological and non-pharmacological approaches as they relate specifically to COPD
- bronchodilator management including methods of delivery & methods of assessing efficacy
- inhaled and oral corticosteroid therapy
- non-pharmacological interventions, including pulmonary rehabilitation, lifestyle advice and self-management techniques
- oxygen therapy
- non-invasive ventilation
- indications for surgery
- criteria for admission and/or management at home, and the problems of respiratory failure.

Advice on treatment options will be based on the best evidence available to the development group. When referring to pharmacological treatments, the guideline will normally recommend use within licensed indications. Exceptionally, and only where the evidence clearly supports it, recommendations for the guideline may recommend use outside the licence indications. The guideline assumes that prescribers will use the Summary of Product Characteristics to inform their prescribing decisions for individual patients.

Audit support within guideline

The guideline will include review criteria and advice for audit.

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